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09/255,655	02/23/1999	MADS LIENDGAARD VIGH	02405.0167	8849
22852	7590	11/08/2004	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005				OWENS JR, HOWARD V
ART UNIT		PAPER NUMBER		
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/255,655
Filing Date: February 23, 1999
Appellant(s): VIGH ET AL.

Charles E. Van Horn
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed May 17, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 13-22 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) *ClaimsAppealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

5447917 Zehner

For the above reasons, it is believed that the rejections should be sustained.

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13 - 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Zehner et al. (Zehner), U.S. Patent no. 5,447,917.

Claims 13-17 are drawn to a method for inducing production of butyrate by bacteria in the human colon comprising administering an effective amount of D-tagatose.

Claims 18 - 22 are drawn to a method for stimulating the growth of lactobacilli and lactic acid bacteria comprising administering D-tagatose to a human in an amount effective to selectively stimulate growth of lactobacilli and lactic bacteria in the human colon.

Zehner anticipates the claims cited supra as it teaches (columns 2-4, claims 1-3) the oral administration of D-tagatose to a human in a dose of 1 g/kg body weight, which encompasses the claimed daily administration of 5 to 30 grams. The stimulation of lactobacilli and the production of butyrate in the human colon is inherently achieved in Zehner via the administration of the D-tagatose compound within the same dosage

range for the treatment of hyperglycemia, diabetes and the inhibition of glycosylation end products (columns 2-3).

Per *Ex parte Novitski*, 26 USPQ2d 1389 (1993), a claimed method of administering a known compound to a subject to achieve an effect not stated in the prior art is anticipated when the differently claimed effect is an inherent feature of the known compound previously administered to the same subject in the prior art. In *Novitski*, a claimed method for protecting plants from nematodes was anticipated by a prior art reference which, although it did not disclose the claimed method *in haec verba*, the prior art did disclose a method of inoculating a plant with "pseudomonas cepacia type Wisconsin 526," which inherently possessed nematode-inhibiting activity an inherent effect not set forth in the prior art (the inherent nematode inhibiting activity was set forth in appellant's specification, not the prior art). Similarly, in the instant claims, the method of administration, the compound and the intended subject are identical to that set forth in the prior art of Zehner; reminiscent of *Novitski*, the only difference is that the inherent effect, stimulation of lactobacilli and the production of butyrate in the human colon, is not stated in the prior art of Zehner.

(11) Response to Argument

Applicant argues that Zehner does not teach and does not recognize that D-tagatose was effective to "selectively" induce butyrate production and to "selectively" stimulate the growth of lactobacilli. As cited above, Per *Ex parte Novitski*, 26 USPQ2d 1389 (1993), a claimed method of administering a known compound to a subject to achieve an effect not stated in the prior art is anticipated when the differently claimed effect is an

inherent feature of the known compound previously administered to the same subject in the prior art. Moreover, there are many decisions in addition to *Ex Parte Novitzki* which have found that the discovery of "a previously unappreciated property of a prior art composition," "a scientific explanation for the prior art's functioning," or "newly discovered results of known processes directed to the same purpose" does not render the old composition new to the discoverer and such discoveries are not patentable because they are inherent in the prior art. See *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999); *Bristol-Myers*, 246 F.3d at 1376. It makes no difference, with respect to anticipation, that Zehner did not recognize that the disclosed method produced this effect. See *In re Woodruff*, 919 F. 2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990) ("It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable."); *Schering Com. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1667 (Fed. Cir. 2003) ('Inherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure.'). The induction of butyrate and the stimulation of the growth of lactobacilli is an affect of the administration of tagatose, wherein this administration is taught in the prior art. Thus the fact that the induction of butyrate and the stimulation of the growth of lactobacilli is not mentioned in Zehner does not mean that there is no inherency. If Zehner taught the induction of butyrate and the stimulation of the growth of lactobacilli, the rejection would not be based on inherency, but anticipation by the literal teachings of the prior art.

With regards to the dose, applicant asserts that Zehner's only teaching of a dose is contained in claim 2 directed to a method of treating diabetes, and it is not a daily dose. However, Zehner actually teaches the dose in example 1 of the disclosure, moreover, the dose is administered within a 24 hr. period which constitutes a daily dose. Applicant argues, p. 6 of the brief, "that assuming weight of the mammal) even if, arguendo, it could be interpreted as a daily dosage amount. For a diabetes patient to receive 30 grams according to the method of Zehner, they could weigh only 30 kg (about 81 pounds). There is no indication that Zehner is treating children or others with a relatively low body weight compared to a normal adult." It should be noted however, that the instant claims are not limited to an adult or a child (emphasis added), only to the administration of 5-30 grams to purportedly achieve the induction of butyrate in a human. Moreover, the prior art does not need to indicate whether it is applicable for an adult or a child when there is a dosage present in the prior art for one of skill in the art to base administration on.

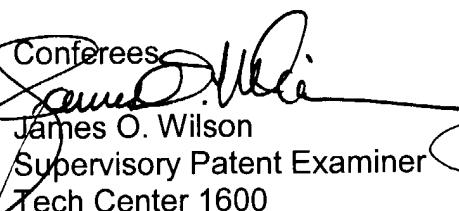
Applicant further argues that there is no inherency because the populations/subjects treated are different. This differentiation is based on the assumption that the teachings of Zehner are limited to a diabetic population. However, the teachings of Zehner are not limited to diabetic populations and the population/subjects as claimed are open to any subject wherein Tagatose is administered within the claimed dosage range. Zehner teaches (columns 2-4, claims 1-3) the oral administration of D-tagatose to a human in a dose of 1 g/kg body weight, which encompasses the claimed daily administration of 5 to 30 grams. Zehner also teaches that diabetes is just one affect of the condition of

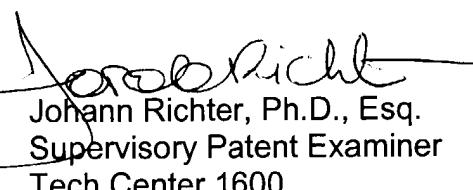
hyperglycemia. Zehner teaches avoiding the condition of hyperglycemia because of the negative effects associated with the increase in blood sugar levels, which is not restricted to a certain patient population and relevant to the dietary habits of both the claimed subjects and those of the prior art. The treatment of hyperglycemia is targeted to control impaired glucose tolerance as well, which is not synonymous with diabetes (see col. 1, lines 25-27). Zehner also teaches the use of D-tagatose to reduce the formation of advanced glycosylated end products which may form from hyperglycemia, wherein the avoidance of these end products is a benefit conferred to both diabetic and non-diabetic subjects. The subjects present in Zehner also are comparable to the claim language in that sugars such as sucrose and glucose are restricted in their diets because they elevate blood sugar (col. 1, , lines 65 – 67), thus comparably, the population of Zehner is in need of administration of the same sugar within the same dosage range to confer a beneficial effect.

Respectfully submitted,

Howard Owens
November 1, 2004

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